

Nuclear Regulatory Commission

§ 35.31

(2) Initiate, recommend, or provide corrective actions; and

(3) Verify implementation of corrective actions.

(b) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Commission terminates the license.

§ 35.25 Supervision.

(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by § 35.11(b) of this part shall:

(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the licensee's written quality management program;

(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and

(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.

(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(c), shall:

(1) Instruct the supervised individual in the preparation of byproduct material for medical use and the principles of and procedures for radiation safety and in the licensee's written quality management program, as appropriate to that individual's use of byproduct material;

(2) Require the supervised individual to follow the instructions given pursuant to paragraph (b)(1) of this section and to comply with the regulations of this chapter and license conditions; and

(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing byproduct material for medical use and the records kept to reflect that work.

(c) A licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

[51 FR 36951, Oct. 16, 1991, as amended at 56 FR 34121, July 25, 1991; 59 FR 61782, Dec. 2, 1994]

§ 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.

(a) The Commission will license mobile nuclear medicine service only in accordance with subparts D, E and H of this part and § 31.11 of this chapter.

(b) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service.

(c) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile nuclear medicine service is under the client's direction.

(d) A mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.31 Radiation safety program changes.

(a) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in §§ 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating

names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license.

(b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

§ 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive¹ is prepared for:

¹If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the

- (i) Any teletherapy radiation dose;
- (ii) Any gamma stereotactic radiosurgery radiation dose;
- (iii) Any brachytherapy radiation dose;
- (iv) Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or
- (v) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(2) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(b) The licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(i) A representative sample of patient and human research subject administrations,

(ii) All recordable events, and

(iii) All misadministrations

to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet

brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.